OCT 3 - 2005

510(k) Summary

K052193

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence

Submitter name, address, and contact

Roche Diagnostics
9115 Hague Road
Indianapolis, IN 46250
317-521-3723

Contact Person: Corina Harper

Date Prepared: August 9, 2005

Device name

Proprietary name: ISE Compensator

Common name: Calibrator

Classification name: Calibrator, Multi-Analyte mixture

Predicate device

The ISE Compensator is substantially equivalent to the cleared ISE Compensation Sera (K870379).

Intended use

ISE Compensator is for use in the calibration of Ion Selective Electrodes on Roche/Hitachi analyzers.

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Substantial equivalence

The ISE Compensator is substantially equivalent to other products in commercial distribution intended for similar use. We claim equivalency to the currently marketed ISE Compensation Sera (K870379).

Substantial equivalence: Similarities

The below tables compare ISE Compensator with the predicate device, ISE Compensation Sera (K870379).

Characteristic	Predicate Device ISE Compensation Sera (K870379)	ISE Compensator
Intended Use	For use in the calibration of Sodium, Potassium, and Chloride on the Boehrienger Mannheim diagnostics/Hitachi Systems with Ion Selective Electrodes.	For use in the calibration of Ion Selective Electrodes on Roche/Hitachi analyzers.
Levels	One	Same
Format	Lyophilized	Liquid
Handling	Add 5.0 mL distilled or deionized water. Allow to stand for 30 minutes. Mix carefully, avoiding the formation of the foam.	Ready to use. Mix well prior to use, avoiding the formation of the foam.
Stability	Unopened: • Store at 2-8°C until expiration date Reconstituted: • 5 days at 2-8 °C • 5 days at -20 °C	Unopened: • Same After opening: • 2 weeks at 2-8 °C

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Substantial equivalence: Similarities (continued)

Characteristic	Predicate Device ISE Compensation Sera (K870379)	ISE Compensator
Matrix	Human serum matrix with added Sodium carbonate, Potassium chloride,, Sodium chloride.	Human serum matrix preparation with defined Sodium, Potassium and Chloride concentrations.

Matrix composition

The table below lists all active ingredients for ISE Compensator.
The active ingredients are spiked into a buffered human serum matrix.

	Components	Concentration
Reactive Components	Na^+ K^+ Cl^-	Refer to target value sheet of package insert.

Performance characteristics

The ISE Compensator was evaluated for value assignment and stability.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 3 - 2005

Ms. Corina Harper, RAC
Regulatory Affairs Consultant
Roche Diagnostics
9115 Hague Road
PO Box 50416
Indianapolis, IN 46250-0416

Re: k052193
Trade/Device Name: ISE Compensator
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIT
Dated: September 13, 2005
Received: September 15, 2005

Dear Ms. Harper:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Carol C. Benson

Carol C. Benson, M.A.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052193

Device Name: ISE Compensator

Indications For Use:

ISE Compensator is for use in the calibration of Ion Selective Electrodes on Roche/Hitachi analyzers.

Prescription Use **XXXX** AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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